

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

This Document Relates to All Actions

Oral Argument Requested

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' JOINT
MOTION TO EXCLUDE OPINIONS OF LAURA R. CRAFT**

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Pursuant to Federal Rules of Evidence 104, 702, and 703, Torrent Pharmaceuticals Ltd., Torrent Pharma Inc., Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis Pharma, Inc., Actavis LLC, Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Princeton Pharmaceutical Inc., and Solco Healthcare US, LLC (collectively, “Defendants”) submit this Memorandum of Law in Support of Defendants’ Joint Motion to Exclude Opinions of Plaintiffs’ expert Laura Craft.

INTRODUCTION

Plaintiffs designated Laura Craft to offer opinions on [REDACTED] [REDACTED] Valsartan containing drugs (“VCDs”) by EmblemHealth and SummaCare, two third-party payors that have assigned their alleged economic loss claims to MSP Recovery Claims, Series LLC (“MSP”). *See* 10/31/22 Expert Decl. of Laura R. Craft, MPH (“Craft Report”) ¶¶ 2-3, 27.¹ In addition to these opinions, Ms. Craft also offered purported rebuttal opinions in deposition testimony on the value consumers place on allegedly contaminated VCDs and on Medicare Part D sponsors’ allocation, characterization, and application of subsidies received from the federal government within the structure of Medicare Part D. Ms. Craft’s opinions should be excluded for multiple reasons.

¹ The Craft Report is attached to the accompanying Certification of Alexia R. Brancato as **Exhibit A**.

First, Ms. Craft's opinions on the [REDACTED] do not "fit" this case because they are irrelevant to any issue related to Defendants' liability *and* they form no part of MSP's damages theory or calculation. Ms. Craft repeatedly testified that she is not offering any opinions on damages and, in fact, does not even know what damages methodology will be applied. And Plaintiffs' actual damages expert, Dr. Rena Conti, Ph.D., does not rely upon (or even cite) [REDACTED].

[REDACTED] Thus, because [REDACTED] are irrelevant to any issue related to Defendants' liability to MSP or to MSP's damages, Ms. Craft's opinions will not be helpful to the trier of fact and should be excluded.

Second, Ms. Craft's opinion on the value of allegedly contaminated VCDs should be excluded because it is outside the scope of her expertise and is not based on any reliable evidence. Ms. Craft, who admits that she is not an expert on consumer behavior, lacks any specialized knowledge, education, training, or experience that would qualify her to opine on the value consumers would ascribe to allegedly contaminated VCDs. Ms. Craft also admits that she has not done any surveys or analyses to determine whether consumers would ascribe any value to allegedly contaminated VCDs. Accordingly, Ms. Craft effectively concedes that

her valuation opinion is predicated on nothing more than her subjective belief or unsupported speculation.

Third, Ms. Craft strays beyond her area of expertise by opining on Medicare Part D plan sponsors' allocation, characterization, and application of federal subsidies within the structure of Medicare Part D and in the Medicare Part D plan sponsors' normal course of business. But Ms. Craft lacks the specialized knowledge necessary to opine on Medicare Part D plan sponsors. As she admitted in her deposition she: (1) has never worked for a Medicare Part D sponsor; (2) has never helped prepare a Medicare Part D bid to the U.S. Centers for Medicare and Medicaid Services ("CMS"); and (3) is not an expert in healthcare or actuary science. As a result, these opinions should be excluded.

For all these reasons, discussed further below, Defendants respectfully submit that the Court should exclude Ms. Craft's opinions in their entirety.

BACKGROUND

Ms. Craft styles herself an "expert in the pharmaceutical industry" and is the co-founder and president of OnPoint Analytics, Inc., "an economic and statistical consulting firm specializing in database services." Craft Rep., Ex. A. In the Craft Report, Ms. Craft opines that: [REDACTED]

[REDACTED] Craft Report at ¶¶ 9-12; [REDACTED]

██████████ *id.* at ¶¶ 13-26; ██████████

██ *id.* at ¶ 27.

Ms. Craft was deposed on January 12, 2023, and offered additional rebuttal opinions not contained in the Craft Report. To start, in response to the expert report of Timothy E. Kosty, Ms. Craft opines that, if the VCDs manufactured by Defendants were contaminated, then those VCDs would be valueless to consumers. Craft Dep. 66:3-69:13.² Ms. Craft admits, however, that she is not an expert in “consumer behavior” and further admits she has not performed any survey or other analysis to determine whether consumers would continue taking VCDs if they were aware of any alleged contamination. *Id.* at 69:14-70:9.

Next, Ms. Craft opines that federal subsidies received by Medicare Part D sponsors do not offset the price paid for any individual drug by Medicare Part D sponsors, like SummaCare and EmblemHealth, and are irrelevant to the calculation of damages that SummaCare and EmblemHealth may have incurred. *See id.* 84:2-111:10. Ms. Craft’s reasoning for this conclusion is twofold. First, Ms. Craft opines that “the purpose and intent behind the creation of Medicare Part D” leads to the conclusion that federal subsidies received by Medicare Part D sponsors are simply “substitute[s] for amounts that would otherwise in a non-subsidized

² The transcript of the deposition of Laura Craft is attached to the accompanying Certification of Alexia R. Brancato as **Exhibit B**.

insurance market be paid by the consumer” (*i.e.*, consumer premiums or co-pays). *Id.* at 93:17-94:11. Second, Ms. Craft opines that any subsidies received by SummaCare and EmblemHealth as a result of Medicare Part D’s risk sharing mechanism are simply “a secondary source of funding to the plan sponsor and nothing more.” *Id.* at 96:11-98:12. Thus, Ms. Craft concludes that any subsidies from CMS are irrelevant to how much Medicare Part D sponsors actually paid for the allegedly contaminated VCDs. *Id.* at 98:13-17.

Despite her lengthy opinions on Medicare Part D sponsors’ allocation, characterization, or application of federal subsidies, Ms. Craft admits that she has never been an employee of a Medicare Part D sponsor; has never helped prepare a CMS bid on behalf of a Medicare Part D sponsor; and has never submitted an expert report on the legislative history or purpose of Medicare Part D. *See id.* at 145:3-146:23. Additionally, Ms. Craft admits she is neither an expert in healthcare nor actuary science. *See id.* at 110:6-10.

LEGAL STANDARD

The Third Circuit has explained that Federal Rule of Evidence 702 embodies a “trilogy of restrictions on expert testimony: qualification, reliability and fit.” *Calhoun v. Yamaha Motor Corp.*, 350 F.3d 316, 321 (3d Cir. 2003) (quoting *Schneider v. Fried*, 320 F.3d 396, 405 (3d Cir. 2003)). To be admissible, expert testimony must be (1) within the expert’s “qualified” area of expertise, (2)

“ground[ed] in the methods and procedures of science,” and (3) “sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute.” *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 588, 589–91 (1993); *see also* Fed. R. Evid. 702. “Rule 702 contains no exception to these requirements, so if they are not satisfied, an expert cannot testify before the ‘trier of fact.’” *UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres*, 949 F.3d 825, 832 (3d Cir. 2020) (quoting Fed. R. Evid. 702). It is Plaintiffs’ burden to establish the admissibility of Ms. Craft’s testimony by a preponderance of the evidence. *See Ctr. City Periodontists, P.C. v. Dentsply Int’l, Inc.*, 321 F.R.D. 193, 202 (E.D. Pa. 2017).

ARGUMENT

I. MS. CRAFT’S OPINIONS [REDACTED] SHOULD BE EXCLUDED BECAUSE THEY WILL NOT ASSIST THE TRIER OF FACT.

Ms. Craft’s opinions on the [REDACTED]

[REDACTED] should be excluded because they will not be helpful to the trier of fact in understanding the issues relevant in this case. A plaintiff must establish that the proffered expert testimony “will assist the trier of fact” in understanding the issues relevant to the case. *Calhoun*, 350 F.3d at 322; *see* Fed. R. Evid. 702(a). To assist the trier of fact, the

testimony must have “a valid scientific connection” to, or “fit,” the relevant inquiry in the lawsuit. *Daubert*, 509 U.S. at 591-92; *Calhoun*, 350 F.3d at 321. “The issue of fit ‘is one of relevance and expert evidence [that] does not relate to an issue in the case is not helpful.’” *In re Hum. Tissue Prod. Liab. Litig.*, 582 F. Supp. 2d 644, 657 (D.N.J. 2008); see *Daubert*, 509 U.S. at 591 (“Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” (citation omitted)). The standard for the “fit” requirement “is ‘not that high’ but is ‘higher than bare relevance.’” *In re Hum. Tissue Prod. Liab. Litig.*, 582 F. Supp. 2d at 657 (citation omitted).

In her report, Ms. Craft opines that: [REDACTED]
[REDACTED] Craft Report
at ¶¶ 9-12; [REDACTED]

[REDACTED] *id.* at ¶¶ 13-26; and [REDACTED]

[REDACTED]
id. at ¶ 27. In other words, Ms. Craft opines that [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

First, Ms. Craft’s opinions are irrelevant to the question of Defendants’ liability to MSP. Ms. Craft’s opinions do not relate to Defendants’ alleged failure

to comply with federal regulations, including cGMPs; they do not relate to the question of whether the VCDs were contaminated, adulterated, or misbranded; and they do not relate to any alleged warranties or representations that Defendants purportedly made or that MSP relied upon. *See generally* Craft Rep.; *see also* Craft Dep. 66:7-9 (“I’m not expressing any opinion about . . . [VCDs] contamination or the level of any such contamination”); *id.* at 72:13-24 (“Q. Ms. Craft, you’re not offering any opinions related to the manufacturing of the valsartan drugs on Exhibit D, correct? A. Only the fact that the data makes it possible to identify who the manufacturers were.”). Put simply, Ms. Craft’s opinions are irrelevant to whether the Defendants breached any express or implied warranties, made any fraudulent or negligent misrepresentations, violated any state consumer protection laws, were unjustly enriched by the sale of allegedly contaminated VCDs, or engaged in any negligent conduct related to VCDs. *See* Third Amended Consolidated Economic Loss Class Action Complaint, ECF No. 1708, ¶¶ 619-823.

Second, Ms. Craft’s opinions are irrelevant to MSP’s damages theory and calculations set forth in Plaintiffs’ damages expert’s report. Ms. Craft confirms in her deposition testimony that she is not offering any opinions on damages. *See* Craft Dep. 99:18-21 (“Now, I’m not – I am not the damages expert in this case. I have not been asked and do not expect to express any opinions about damages . . .

.’); *id.* at 144:6-11 (“So I don’t know what the damage methodology will be in this case. . . . I’m not expressing opinions about damages.”). Not only does Ms. Craft offer no direct opinions on damages in her report, but Ms. Craft’s opinions also form no part in Plaintiffs’ damages expert Dr. Rena Conti, Ph.D.’s calculation of the economic loss and unjust enrichment damages incurred by MSP due to the purchases of VCDs. In fact, Dr. Conti’s report on damages does not contain a single reference to any of Ms. Craft’s opinions. *See generally* Damages Expert Decl. of Rena Conti, Ph.D.³

Thus, because Ms. Craft’s opinions on the [REDACTED] [REDACTED] have no bearing on any issue of Defendants’ liability or MSP’s damages theory or calculation, Ms. Craft’s opinions will not assist the trier of fact in understanding the evidence or determining a fact in issue. *See Daubert*, 509 U.S. at 591 (“Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.”); *see also Ctr. City Periodontists, P.C.*, 321 F.R.D. at 203 (excluding expert’s testimony where it did “not reach the relevant factual issues” and could

³ The Damages Expert Declaration of Rena Conti, Ph.D., dated February 3, 2023, is attached to the accompanying Certification of Alexia R. Brancato as **Exhibit C**.

not “assist the trier of fact in any other way”). Accordingly, Ms. Craft’s opinions on [REDACTED]

II. MS. CRAFT’S OPINIONS REGARDING THE VALUE OF ALLEGEDLY CONTAMINATED VCDS SHOULD BE EXCLUDED.

Ms. Craft is not qualified to offer an opinion on the value that a consumer would place on an allegedly contaminated VCD, and any such opinion is unreliable as it is predicated on Ms. Craft’s subjective belief or unsupported speculation.

A. Ms. Craft’s Opinion That Consumers Would Consider Allegedly Contaminated VCDs Valueless Falls Outside Of Ms. Craft’s Theoretical Area Of Expertise And Should Be Excluded.

It is incumbent on the proponent of expert testimony to demonstrate that the expert is qualified “to render an opinion” predicated on his or her “specialized expertise.” *In re Hum. Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d at 655 (citation omitted). Despite courts’ liberal treatment of the qualification requirement, the Third Circuit recognizes that an expert “may be generally qualified” but “lack qualifications to testify outside his area of expertise.” *Calhoun*, 350 F.3d at 322. Put differently, although an expert’s “background, education, and training may provide . . . general knowledge” sufficient to “testify about general matters, more specific knowledge is required to support more specific opinions.” *Id.*

Ms. Craft holds a Master of Public Health from the University of California, Berkeley, in the field of public health. Craft Rep. ¶ 4. Ms. Craft is currently the president of OnPoint Analytics, Inc., “an economic, statistical, and financial

consulting firm specializing in data analytics for complex litigation.” *Id.* at ¶ 5. Ms. Craft also co-authored a book entitled *Empirical Challenges in Pharma Litigation*, which Ms. Craft describes as detailing, comparing, and outlining the usefulness of “various data sets, including those privately developed and maintained by drug manufacturers and their partners, government data, and data collected and sold by commercial services for use by industry participants and analysts.” *Id.* at ¶ 6. Ms. Craft has co-developed and taught courses entitled *Data and Empirical Challenges in Pharmaceutical Litigation* and *Antitrust Claims Involving Pharmaceutical Products* and has worked on “numerous class actions . . . in which [her] key functions included developing databases of discrete transactions from multiple data sources, and both identifying class members and isolating and removing those who are uninjured or subject to specific class exclusions.” *Id.* at ¶¶ 6-7.

Ms. Craft, however, strays well beyond her theoretical area of expertise in opining that, if the VCDs manufactured by Defendants were contaminated, then those VCDs would be valueless to consumers. Craft Dep. 66:3-69:13. Ms. Craft admits that she is not an expert in “consumer behavior” and admits she has not performed any survey or other analysis to determine whether consumers would continue taking VCDs if they were aware of the alleged contamination. *Id.* at 69:14-70:9. Ms. Craft’s CV is likewise devoid of qualifications that even hint at

specialized knowledge or experience related to analyzing how a consumer would value an allegedly contaminated pharmaceutical drug. *See* Craft Rep., Ex. A.

In cases like this, where an expert offers opinions outside of her area of expertise, courts across the country have not hesitated in excluding the unqualified testimony. *See, e.g., Lucido v. Nestle Purina Petcare Co.*, 217 F. Supp. 3d 1098, 1103 (N.D. Cal. 2016) (precluding a veterinarian that had scientific, technical, or other specialized knowledge related to her job as a veterinarian from providing “opinions about what a reasonable consumer would consider material” when purchasing dog food because such opinions did not flow from her “specialized knowledge as a veterinarian”); *Wolf v. Hewlett Packard Co.*, No. CV 15-01221 BRO (GJSx), 2016 WL 7743692, at *6 (C.D. Cal. Sept. 1, 2016) (finding an expert not qualified to opine on the prediction of consumer behavior where, *inter alia*, the expert had “no background in consumer psychology,” “no educational or professional background in survey design or sampling,” and no “peer-reviewed articles on discrete choice modeling, conjoint experiments or analysis, or survey design/sampling”).

Accordingly, because Ms. Craft strayed outside her area of expertise in opining on consumer behavior and how consumers would value VCDs, these opinions should be precluded. *See, e.g., Wolf*, 2016 WL 7743692, at *6.

B. Ms. Craft's Opinion On The Value Of VCDs Is Also Unreliable As It Is Predicated On Ms. Craft's Baseless Speculation Or Subject Belief.

Ms. Craft's opinion on the value of VCDs to consumers is also unreliable as it is based solely on her subjective belief or unsupported speculation. An expert "must have good grounds for his o[r] her belief," and the opinion cannot be based upon "subjective belief or unsupported speculation." *Calhoun*, 350 F.3d at 321.

Ms. Craft opines that, if the VCDs manufactured by Defendants were contaminated, then those VCDs would be valueless to consumers. Craft Dep. 66:3-69:13. But Ms. Craft concedes that she has not performed any survey or other analysis to ascertain consumers thoughts or views on the value of allegedly contaminated VCDs or determine whether consumers would continue taking VCDs if they were aware of the alleged contamination. *Id.* at 70:3-70:9.

Clearly, then, Ms. Craft's opinion on the value of allegedly contaminated VCDs must be based on her subjective belief or unsupported speculation. Accordingly, Ms. Craft's testimony is unreliable and should be excluded for this reason, as well. *See Yazujian v. PetSmart*, 729 F. App'x 213, 215–16 (3d Cir. 2018) (excluding expert testimony that "constituted no more than 'subjective belief or unsupported speculation'" (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994)); *Ruggiero v. Yamaha Motor Corp., U.S.A.*, No. 15-49 (JBS/KMW), 2017 WL 1197755, at *7 (D.N.J. Mar. 31, 2017) (holding an expert

opinion was unreliable where the expert, “in developing it, . . . failed to perform any tests . . . leaving his conclusion to be, at best, an educated guess”), *aff’d*, 778 F. App’x 88 (3d Cir. 2019).

III. MS. CRAFT IS ALSO NOT QUALIFIED TO OFFER AN OPINION ON MEDICARE PART D SPONSORS, INCLUDING THEIR ALLOCATION, CHARACTERIZATION, OR APPLICATION OF SUBSIDIES.

Ms. Craft also steps beyond any theoretical area of expertise in opining that federal subsidies received by Medicare Part D sponsors do not offset the price paid for any individual drug by Medicare Part D sponsors, like SummaCare and EmblemHealth, and are irrelevant to the calculation of damages that SummaCare and EmblemHealth may have incurred. *See* Craft Dep. 84:2-111:10. Although Ms. Craft has some experience with Medicare Part D generally, Ms. Craft lacks any specialized knowledge as to how Medicare Part D sponsors operate in practice, including how they allocate or characterize subsidies received from the federal government. Indeed, Ms. Craft admits that she has never been an employee of a Medicare Part D sponsor and has never helped prepare a CMS bid on behalf of a Medicare Part D sponsor. *See id.* at 145:3-146:23. As a result, Ms. Craft lacks specialized knowledge as to how Medicare Part D sponsors actually allocate, characterize, or apply federal subsidies in their normal course of business. Ms. Craft also confirmed that she is neither an expert in healthcare or actuary science

and has never authored an expert report on the legislative history or purpose of Medicare Part D. *See id.* at 110:6-10, 146:14-22.

Accordingly, Ms. Craft's testimony on Medicare Part D sponsors allocation, characterization, and application of federal subsidies in their normal course of business should be excluded. *See Rheinfrank v. Abbott Labs., Inc.*, 680 Fed. App'x 369, 380 (6th Cir. 2017) (affirming exclusion of expert testimony "on regulatory areas in which" the experts "had neither specialized training nor professional experience"); *Rowland v. Novartis Pharms. Corp.*, 9 F. Supp. 3d 553, 570 (W.D. Pa. 2014) (excluding testimony because "the Court c[ould] imagine no reason why . . . an oncologist . . . should be permitted to testify about . . . general dental condition"); *Ferris v. Pa. Fed'n. Bhd. of Maint. of Way Emps.*, 153 F. Supp. 2d 736, 743-44 (E.D. Pa. 2001) (excluding doctor's testimony on causation of medical conditions related to anxiety and depression where the doctor was trained and practiced as a pathologist and pain management specialist).

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court exclude the opinions of Plaintiffs' expert Laura Craft.

Dated: March 13, 2023

Respectfully submitted,

/s/ Alexia R. Brancato

KIRKLAND & ELLIS LLP
Jay P. Lefkowitz
Devora W. Allon
Alexia R. Brancato
Brittney Nagle
601 Lexington Avenue
New York, New York 10022
Tel: (212) 446-5967
Fax: (212) 446-6460
lefkowitz@kirkland.com
devora.allon@kirkland.com
alexia.brancato@kirkland.com
brittney.nagle@kirkland.com

*Attorneys for Torrent
Pharmaceuticals Ltd. and Torrent
Pharma Inc.*

GREENBERG TRAURIG, LLP
Lori G. Cohen
Victoria Davis Lockard
Steven M. Harkins
Terminus 200
3333 Piedmont Road, N.E., Ste. 2500
Atlanta, Georgia 30305
Tel: (678) 553-2100
Fax: (678) 553-2386
CohenL@gtlaw.com
LockardV@gtlaw.com
HarkinsS@gtlaw.com

*Attorneys for Teva Pharmaceuticals
USA, Inc., Teva Pharmaceutical
Industries Ltd., Actavis Pharma, Inc.,
and Actavis LLC*

SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP
Jessica Davidson, Liaison Counsel for
Manufacturer Defendants
Allison M. Brown
One Manhattan West
New York, NY 10001
Telephone: (212) 735-2588
Facsimile: (917) 777-2588
jessica.davidson@skadden.com
allison.brown@skadden.com

Nina R. Rose
1440 New York Ave., N.W.
Washington, D.C. 20005
Tel: (202) 371-7000
Fax: (202) 661-0525
nina.rose@skadden.com

*Attorneys for Zhejiang Huahai
Pharmaceutical Co, Ltd., Huahai
U.S., Inc., Princeton Pharmaceutical
Inc., and Solco Healthcare US, LLC*

CERTIFICATE OF SERVICE

I, Alexia R. Brancato, an attorney, hereby certify that on March 13, 2023, I caused a copy of the foregoing document to be served on all counsel of record via CM/ECF.

/s/ Alexia R. Brancato
Alexia R. Brancato
Kirkland & Ellis LLP